

§ 52h.4

42 CFR Ch. I (10–1–03 Edition)

Human Services (45 CFR part 11), implementing regulations and chapter 9 of the Department of Health and Human Services General Administration Manual¹ will govern the establishment and operation of peer review groups, including that meetings shall be open to the public except as determined by the Secretary.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, and the Administrator of the Health Resources and Services Administration will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9 and 52h.10 within their respective agencies.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289f–4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§ 52h.4 Composition of peer review groups.

(a) To the extent applicable, the selection and appointment of members of peer review groups and their terms of service will be governed by Chapter 9 of the Department of Health and Human Services General Administration Manual.¹

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, taking into account, among other factors:

(1) The level of formal scientific or technical education completed or experience acquired by the individual;

(2) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigator, assistant) in which the individual has done so, and the quality of such research;

¹The Department of Health and Human Services General Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Printing Office, Washington, DC 20402.

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; and

(4) The need for the group to have included within its membership experts from various areas of specialization within relevant scientific or technical fields.

(c) Not more than one-fourth of the members of any peer review group to which these regulations are applicable may be officers or employees of the United States. For purposes of the preceding sentence, membership on such groups does not make an individual an officer or employee of the United States.

§ 52h.5 Conflict of interest.

(a) Members of peer review groups covered by this part are subject to relevant provisions in title 18 of the United States Code, relating to criminal activity, the Department of Health and Human Services Standards of Conduct (45 CFR part 73), and Executive Order 11222, as amended.

(b) In addition to any restrictions imposed under paragraph (a) of this section:

(1) No member of a peer review group may participate in or be present during any review by said group of a grant application, contract project, or contract proposal in which, to the member's knowledge, any of the following has a financial interest: (i) The member or his or her spouse, parent, child, or partner, (ii) any organization in which the member or his or her spouse, parent, child, or partner is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated, or (iii) any organization with which the member or his or her spouse, parent, child, or partner is negotiating or has any arrangement concerning prospective employment or other similar association.

(2) In the event any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a grant application, contract